

REMARKS

Claims 22-50 and 52-55 are in this application. Claim 51 has been cancelled.

In view of the cancellation of claim 51 and the amendment of claims 39-50, 52, 54 and 55 it is respectfully requested that the rejections under 35 USC 112 be withdrawn.

According to the Official Action, claims 38-45 and 54-55 are rejected under 35 USC 103(a) as being obvious over de Souza et al. (US patent 6,514,986) in view of de Souza et al. (US patent 6,608,078) taken with Leyden. In addition, claims 45 and 51-52 are rejected as being obvious over de Souza et al. in view of the references cited above and further in view of Katsambas et al. These rejections are respectfully traversed.

It is applicants' position that the examiner is basing these rejections on impermissible hindsight. According to MPEP 2141 when applying 35 USC 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and (D) reasonable expectation of success is the standard with which obviousness is determined.

A reference must be considered for what it would teach someone skilled in the art at the time the invention was made and not be applied based on "hindsight". See *Panduit Corp. V. Dennison Manufacturing Co.*, 227 USPQ 337, 343 (Fed. Cir. 1985):

It is impermissible to first ascertain factually what applicants did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants' invention from such prior art.

In making its obviousness determination, a court must view the prior art without reading into that art the patent's teachings. *Vandenberg v. Dairy Equipment*, 224 U.S.P.Q. 195 (Fed. Cir. 1987) citing *In re Sponnoble*, 160 U.S.P.Q. 237 (CCPA 1969). In *Uniroyal . Rudkin-Wiley*, 50 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988) the CAFC stated:

The obviousness standard, while easy to expound, is sometimes difficult to apply. It requires the decision maker to return to the time the invention was made. The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time...That which may be clear and thus obvious to a court, with the invention fully diagramed and aided by experts in the field, may have been a breakthrough of substantial dimension when first unveiled [citations omitted]. In this case we are convinced that the district court misapplied the obviousness standard. It has impermissibly used hindsight to reconstruct the claimed invention from prior art with the invention before it and aided by Uniroyal's expert, rather than viewing the invention from the position of a person of ordinary skill at the time it was made. When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.

As is well-known to the Examiner, the standard test used to establish *prima facie* obviousness is the test set out by the Supreme Court in *Graham v. John Deere* (383 US

1, 148 USPQ 459 (1966)). To determine whether a claim is *prima facie* obvious:

- 1) the scope and content of the prior art are to be determined;
- 2) the differences between the prior art and the claims at issue are to be ascertained; and
- 3) the level of ordinary skill in the pertinent art resolved.

In addition, according to MPEP 2141, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n. 5 (Fed. Cir. 1986), when applying 35 USC 103, the following tenets of patent law must be adhered to:

- 1) the claimed invention must be considered as a whole;
- 2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; and
- 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.

The reason, suggestion or motivation to combine references may be found explicitly or implicitly. While the references need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability must be clear and particular. *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000). See also *KSR v. Teleflex*, 550 US ___, 127 S. Ct. 1727 (2007).

U.S. Patent 6,608,078 does not disclose the compounds as presently claimed in claim 38 and the Examiner's attention is drawn to column 6, lines 5-6 of the patent where it is stated specifically that when R₁ is H, R₂ cannot be H. Therefore, since this patent specifically excludes the compounds that are claimed, this patent cannot be combined with other references as a basis for stating that the claims are obvious. The examiner refers to the disclosure in column 8, lines 33-34 that the arginine salt form of nadifloxacin can be combined with other active ingredients. However, the only active ingredients mentioned are other antibacterial agents.

Leyden refers to the use of retinoids in combination with antibiotics, however, Leyden does not disclose or suggest compositions that include both an antibiotic or specifically a nadifloxacin type antibiotic with a retinoid. In fact, Leyden discloses combinations of topical and systemic therapy.

Katsambas also discloses lists and types of drugs including nadifloxacin and retinoids and like Leyden does not disclose nor suggest compositions containing these components together.

Therefore, since there is no combination of the references that teach or suggest that the compounds of claim 38 and 39 can be combined into a single composition, it is respectfully requested that these rejections be withdrawn.

Accordingly, applicants submit that the present application is in condition for allowance.


Respectfully submitted,
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